

Section 10. 510(k) Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

DEC 10 2009

The Assigned 510(k) number is: K092099

1. Submitter's Identification:

TaiDoc Technology Corporation

6F, No.127, Wugong 2nd Rd., Wugu Township, Taipei County, 248, Taiwan

Correspondence:

Debra Liang

Regulatory Affairs Specialist

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Date of submission:

2. Device name:

Proprietary name: FORA TD-4251 / U-RIGHT TD-4252/ U-RIGHT

TD-4253/U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring System, model
no. TD-4251A/ TD-4252C/ TD-4253A/ TD-4254A

Regulatory information:

A. Regulation section: 21 CFR 862.1345 Glucose Test System

B. Classification: Class II

C. Product Code: CGA, Glucose Oxidase, Glucose
NBW, System, Test, Blood Glucose, Over The Counter

D. Panel: Chemistry (75)

3. Intended Use:

FORA TD-4251 / U-RIGHT TD-4252/ U-RIGHT TD-4253/U-RIGHT TD-4254

No-Coding Blood Glucose Monitoring System, model no. TD-4251A/ TD-4252C/ TD-4253A/ TD-4254A are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

4. Device Description:

FORA TD-4251 / U-RIGHT TD-4252/ U-RIGHT TD-4253/U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring System consists of Glucose meter, Test Strips, Two levels of Control solution, A commercially available (510(k) cleared) lancing device and sterile Lancets, User Manual, and Storage Pack.

5. Substantial Equivalence Information:

A. Predicate device name:

FORA TD-4251/ URIGHT TD-4252 / URIGHT TD-4254 Blood Glucose Monitoring System

B. Predicate K number: K082482

C. Comparison with predicate:

The modified FORA TD-4251 / U-RIGHT TD-4252/ U-RIGHT TD-4253/U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring System, model no. TD-4251A/ TD-4252C/ TD-4253A/ TD-4254A have the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life
- packaged using the same materials, and
- Manufactured by the same process.

The modifications encompass:

- A modification in the software of the glucose meter
- Modification in the physical appearance
- Labeling change due to the software modification

6. Test Principle:

The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose oxidase.

7. Performance Characteristics:

The FORA TD-4251 / U-RIGHT TD-4252/ U-RIGHT TD-4253/U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring Systems have the same performance characteristics as the predicate device.

A comparison of system accuracy performance demonstrated that the FORA TD-4251 /U-RIGHT TD-4252/ U-RIGHT TD-4253/U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring System, model no. TD-4251A/ TD-4252C/ TD-4253A/ TD-4254A and the currently marketed FORA TD-4251/ URIGHT TD-4252 / URIGHT TD-4254 Blood Glucose Monitoring System are substantially equivalent. A mechanical resistance test showed that the model TD-4253 meet the requirement of EN ISO 15197.

Software verification and validation testing confirmed that the performance, safety and effectiveness of the FORA TD-4251 / U-RIGHT TD-4252/ U-RIGHT TD-4253/U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring System, model no. TD-4251A/ TD-4252C/ TD-4253A/ TD-4254A are equivalent to the predicate device.

8. Conclusion:

Based on the information provided in this submission, the FORA TD-4251 / U-RIGHT TD-4252/ U-RIGHT TD-4253/U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring System, model no. TD-4251A/ TD-4252C/ TD-4253A/ TD-4254A are substantially equivalent to the predicate FORA TD-4251/ URIGHT TD-4252 / URIGHT TD-4254 Blood Glucose Monitoring System.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Silver Spring, MD 20993-0002

TaiDoc Technology Corporation
c/o Debra Liang
Regulatory Affairs Specialist
6F, No.127, Wugong 2nd Rd., Wugu Township
Taipei County, Taiwan

DEC 10 2009

Re: k092099
Trade/Device Name: FORA TD-4251/U-RIGHT TD-4252/ U-RIGHT TD-4253/ U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: November 11, 2009
Received: November 12, 2009

Dear Ms. Liang

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 7 Indications for Use

Indications for Use

510(k) Number: K092099

Device Name: FORA TD-4251 / U-RIGHT TD-4252/ U-RIGHT TD-4253/U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring System, model no. TD-4251A/ TD-4252C/ TD-4253A/ TD-4254A

Indications for Use:


FORA TD-4251 / U-RIGHT TD-4252/ U-RIGHT TD-4253/U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring System, model no. TD-4251A/ TD-4252C/ TD-4253A/ TD-4254A are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The alternative site testing in the FORA TD-4251 / U-RIGHT TD-4252/ U-RIGHT TD-4253/U-RIGHT TD-4254 No-Coding Blood Glucose Monitoring System can be used only during steady-state blood glucose conditions.

Prescription Use _____ And/Or Over the Counter Use X
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092099

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